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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,414	07/30/2003	Zheng Z. Wu	54334US019	9005

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/630,414	WU ET AL.	
	Examiner	Art Unit	
	MINA HAGHIGHATIAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/02/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 10/27/08 and Amendments filed on 12/04/08, Terminal Disclaimer filed on 10/27/08 and an IDS filed on 01/02/09. Claim 29 has been amended. No claims have been cancelled or newly added. Accordingly, claims **29-37** remain pending.

Terminal Disclaimer

The terminal disclaimer filed on 10/27/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of said patents (6,610,273 and 6,315,985) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tzou et al (5,776,433) in view of Saidi et al (6,241,969).

Tzou et al teach pharmaceutical aerosol formulations comprising flunisolide, ethanol and a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3-heptafluoropropane, and a mixture thereof (see abstract). The said formulations are in **solution** form and comprise an effective amount of flunisolide, a propellant and **ethanol** in an amount effective to solubilize the flunisolide in the formulation (see col. 1, line 52 to col. 2, line 4). The formulations are filled in an aerosol canister equipped with conventional valves, preferably metered dose valves (see col. 3, lines 40-48). It is further disclosed that "certain containers enhance the chemical stability of certain formulations of the invention and/or minimize the absorption of flunisolide onto the container walls; therefore, it is preferred to contain a formulation of the invention within a **glass aerosol vial** or an **aluminum aerosol vial having an interior formulation chamber coated with a resin that is inert** to flunisolide and preferably does not absorb flunisolide from the formulation. Suitable resins for coating the formulation chamber include materials commonly employed as interior can coatings, such as epoxy resins (e.g. **epoxy-phenolic resins** and epoxy-urea-formaldehyde resins)" (see col. 4, lines 1-14). Tzou et al lacks specific disclosure on other corticosteroids such as dexamethasone, betamethasone, etc.

Saidi et al teach compositions containing corticosteroids in a **dissolved** state for pulmonary or nasal delivery. The said corticosteroids include dexamethasone,

betamethasone, flunisolide, **triamcinolone acetonide**, beclometasone, etc. Particularly preferred are dexamethasone, betamethasone, flunisolide, etc (see abstract and col. 6, lines 8-30). The formulation contains co-solvents such as **ethanol** and propylene glycol (see col. 8, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Tzou et al on solution formulations containing active agents such as flunisolide (a corticosteroid), propellants and ethanol for inhalation stored in and delivered by a metered dose inhaler having a coated aluminum interior to have looked in the art for other suitable active agents such as dexamethasone, betamethasone as taught by Saidi et al with the reasonable expectation of successfully preparing a formulation that is stable, effective and easy to administer. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and **the combination would have yielded predictable results** to one of ordinary skill in the art at the time of the invention. Furthermore, the claim would have been obvious because the **substitution of one known element for another** would have yielded predictable results to one of ordinary skill in the art at the time of invention.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tzou et al (5,776,433) in view of Saidi et al (6,241,969) as applied to claims 29-36 above and further in view of Randall (3,923,484).

The combination of references applied above, Tzou et al in view of Saidi et al, lack specific disclosure on fused silica glass.

Randall et la teach a method of producing a glass body composed of two or more oxides (see abstract). The said method involves doping a fused oxide glass, such as **fused silica glass** produced by flame hydrolysis, with a second oxide (see col. 2, lines 39-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tzou et al on solution formulations containing active agents such as flunisolide (a corticosteroid), propellants and ethanol for inhalation stored in and delivered by a metered dose inhaler having a glass vial or coated aluminum interior and the teachings of Saidi et al on other corticosteroids such as dexamethasone, betamethasone with the glass body of Randall et al with a reasonable expectation of successfully preparing a formulation that is stable, and stored in a suitable container. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and **the**

combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 29-31 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porush et al (2,868,691) in view of Ashurst et al (6,143,277).

Porush et al teach a self-propelling composition for inhalation therapy containing a salt of isoproterenol or epinephrine. The said compositions comprise a **medicament dissolved** in a non-toxic liquid propellant in the nature of fluorinated or fluorochlorinated lower aliphatic hydrocarbon, preferably with the aid of a **co-solvent** for both the medicament and the propellant (col. 1, lines 62-72). A suitable co-solvent is **ethanol** (see paragraph bridging columns 2 and 3). The medicament employed in the said composition is one which is therapeutically effective when administered by inhalation and which may be brought into **stable solution**. Such medicaments include **steroids** (col. 2, lines 41-60). Porush lacks disclosure on specific device, active agent, or propellants as claimed.

Ashurst et al teaches a metered dose inhaler having part or all of its internal metallic surfaces coated with one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation (see abstract). Preferred drug formulations contain salmeterol in combination with an anti-inflammatory steroid such as flunisolide, beclomethasone, budesonide,

triamcinolone acetonide, etc (see col. 3, lines 15-30). A polar co-solvent such as **ethanol**, isopropanol and propylene glycol may be added (col. 3, lines 6-12).

Ashurst's compositions contain propellants and suitable propellants include HFA 134a and HFA 227 (see col. 3, lines 55-67). The MDI cans and caps are made of aluminum, an alloy of aluminum, stainless steel or they may be fabricated from **glass** or plastic. The internal surface of the inhaler can be **coated** by a fluorocarbon polymer such as perfluoroalkoxyalkylene (see col. 4, line 47 to col. 5, line 25). It is also disclosed that MDI cans may be coated by the means known in the art of metal coating such as spray-coating (see paragraph bridging col. 5 and col. 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Porush et al on solution formulations containing steroids for inhalation to have looked in the art for specific active agents, propellants and device as taught by Ashurst et al with the reasonable expectation of successfully preparing a formulation that is stable, effective and easy to administer. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porush et al (2,868,691) in view of Ashurst et al (6,143,277) as applied to claims 29-31 and 34-36 above and further in view of Ercoli et al (3,755,302).

The combined references of Porush et al and Ashurst et al, discussed above, lack disclosure on specific corticosteroids of claims 32 and 33.

Ercoli et al teach process for the production of 17-monoesters of 17α, 21-dihydroxy-20-ketosteroids (see abstract). Such ketosteroids include dexamethasone and betamethasone 17-valerate (see Table 1 and Examples).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the solution formulations of the combined references to have looked in the art for other suitable steroids because preparing more stable solution formulations for aerosol delivery with other active agents would provide patients and health care providers with more options and better therapeutic outcomes. In other words, the claim would have been obvious because **the substitution of one known element for another** would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blondino et al (6,290,930) in view of Ashurst et al (6,143,277) and in view of Ercoli et al (3,755,302).

Blondino et al discloses a **stabilized medicinal aerosol solution** formulations adapted for use in a pressurized aerosol container. The aerosol formulation is formulated from a composition containing **budesonide**, at least one fluoroalkane propellant and a co-solvent (see abstract). It is disclosed that the solution aerosol compositions are filled in a plastic coated glass bottle or an aluminum canister (see col. 4, lines 15-27). The preferred propellants include HFA 134 and HFA 227 or a mixture thereof (col. 3, lines 12-24). Blondino et al lack specific disclosure on other suitable 20-ketosteroid drugs other than budesonide and coated metal canisters.

Ashurst et al, discussed above, teaches a metered dose inhaler having part or all of its internal metallic surfaces coated with one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation. Preferred drug formulations contain salmeterol in combination with an anti-inflammatory steroid. A polar co-solvent such as **ethanol**, isopropanol and propylene glycol may be added. The MDI cans and caps are made of aluminum, an alloy of aluminum, stainless steel or they may be fabricated from **glass** or plastic.

Ercoli et al teach process for the production of 17-monoesters of 17α, 21-dihydroxy-20-ketosteroids (see abstract). Such ketosteroids include dexamethasone and betamethasone (see Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the solution formulations of Blondino et al to have looked in the art for other suitable steroids and other forms of internal coating for the canisters because preparing more stable solution formulations for aerosol delivery with other active agents would provide patients and health care providers with more options and better therapeutic outcomes. Also one would be motivated to employ coated canisters for improved stability of the formulation. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have **yielded predictable results** to one of ordinary skill in the art at the time of the invention.

Claims 29-31 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al (6,131,566) in view of Saidi et al (6,241,969).

Ashurst et al teaches a metered dose inhaler having part or all of its internal metallic surfaces coated with one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation

(see abstract). Preferred drug formulations contain salmeterol in combination with an anti-inflammatory steroid such as fluticasone, beclomethasone, **budesonide,** **triamcinolone acetonide**, etc (see col. 3, lines 15-30).

Ashurst's compositions contain propellants and suitable propellants include HFA 134a and HFA 227 (see col. 3, lines 55-67). The MDI cans and caps are made of aluminum, an alloy of aluminum, stainless steel or they may be fabricated from **glass** or **plastic**. The internal surface of the inhaler can be **coated** by a fluorocarbon polymer (see col. 4, line 47 to col. 5, line 25). It is also disclosed that MDI cans may be coated by the means known in the art of metal coating such as spray-coating (see paragraph bridging col. 5 and col. 6). Ashurst et al's formulations are in suspension form and lacks specific disclosure on solutions.

Saidi et al teach compositions containing corticosteroids in a dissolved state in the composition. The said corticoteroids include betamethasone, budesonide, triamcinolone, dexamethasone, dexamethasone 21-isonicotinate (see abstract and col. 6, lines 8-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Ashurst et al on formulations containing active agents such as corticosteroids for inhalation stored in and delivered by a metered dose inhaler having a non-metal interior to have looked in the art for other dosage forms of the formulation such as solutions as taught by Saidi et al with the

reasonable expectation of successfully preparing a formulation that is stable, effective and easy to administer. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al (6,131,566) in view of Saidi et al (6,241,969) as applied to claims 29-31 and 34-36 above and further in view of Randall et al (3,923,484)

The combination of Ashurst et al and Saidi et al, discussed above, lacks specific disclosure on the fused silica glass of claim 37.

Randall et al, discussed above, teach a method of producing a glass body composed of two or more oxides (see abstract). The said method involves doping a fused oxide glass, such as **fused silica glass** produced by flame hydrolysis, with a second oxide (see col. 2, lines 39-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the references because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **29-37** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-37 of copending Application No. 11/061,529 (US 20050220717). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Specifically, the reference claims are drawn to a medicinal aerosol solution metered dose inhaler product comprising a 20-ketosteroid drug and one or two HFA propellants in a container that has an anon-metal interior surface. The instant claims are drawn to a pressurized metered dose inhaler containing a solution of an active agent (such as a 20-ketosteroid) an HFA propellant, having part or all of its internal surface consisting of a stainless steel, aluminum or coated with an inert coating. Although the instant claims are of a slightly broader scope, they are obvious over the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 10/27/08 have been fully considered but they are not persuasive.

Applicant argues that "Tzou et al discloses that a solution formulation of flunisolide has improved chemical stability in a glass or resin coated aluminum canister. Tzou et al is silent as to other steroids". This is correct, however not a persuasive argument. Tzou et al teaches chemically stable formulations of corticosteroid, flunisolide which is 20-ketosteroid drug dissolved in the carrier. The only missing element fro Tzou et al is the specific active agents of the instant claims. The species that fall into the class of "20-ketosteroid" corticosteroids are a limited number and that one of ordinary skill in the art would have been motivated to have employed other species in the same formulation as taught by Tzou et al, with expected results. Simply a substitution of active agent for another.

Applicant states that "the present inventors discovered specifically why some steroids degrade in solution and some do not, and how to improve stability of the unstable ones". This is not persuasive. Instant claims are drawn to a medicinal aerosol solution formulation, or in another words, the claims are "product" claims. Tzou et al teaches the solution formulations and the device exactly as claimed. The only difference is the active agent, which is taught by Saidi et al. It has been clearly shown that one of

ordinary skill would have been able to and would have had motivation to substitute one active for another and would have arrived at the same formulation. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., chemical stability) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Again the instant claims are product claims and not a method of stabilizing specific formulations.

Applicant argues against the teachings of Saidi et al and states that Saidi et al discloses aqueous solutions of many steroids, which are all chemically stable. Applicant then concludes that Said is effectively teaching away. This is not persuasive because as mentioned above, Tzou et al teaches solution formulations of steroid, flunisolide. One of ordinary skill in the art would have been motivated to have employed any steroid ion the same formulation system. Saidi was relied upon for its disclosure of specific steroids in a solution form. Furthermore, "stability" or "stable" are relative terms and any formulation would have a certain degree of stability for a certain length of time. Applicant is arguing features that are not patentable elements in the claims. Even if resolving the stability issue was the object of the present invention, it is stated that "to meet obviousness, prior art does not need to recognize or resolve the same problem as claimed. In *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007), Court ruled that, obviousness can come from the references or from the knowledge of a person having ordinary skill in the art. In fact, the Supreme Court stated

that the Federal Circuit had erred in four ways, one of which is "by holding that courts and patent examiners should look only to the problem the patentee was trying to solve" and second is "by assuming that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem". See KSR, 82 USPQ2d at 1397.

Applicant argues that Randall teaches a method of making fused silica glass bodies, but not glass coatings on metal. While this is correct it is not persuasive because Tzou et al teaches canisters that have glass on their internal surface or have a chamber coated with a resin that is inert to flunisolide. Randall teaches a glass body composed of two or more oxides which may be a fused oxide glass, such as **fused silica glass.** Thus it would have been obvious to one of ordinary skill in the art to have selected fused silica glass as the inert resin for coating.

Applicant argues that Ashurst is directed to aerosol suspension compositions and not to solutions as claimed. Applicant also argues that Ashurst discloses formulations comprising albuterol and not corticosteroids. This is not persuasive. Applicant is attacking references individually, while the claims have been rejected over a combination of two references and under rules of obviousness. Ashurst teaches formulations (in suspension form) for aerosol delivery comprising salmeterol (albuterol) in combination with corticosteroids. Ashurst also teaches advantages of inner coating of the canister. Porush et al teaches solution formulations of corticosteroids for inhalation to pulmonary subsystem. Applicant has not shown that the combination of the references would not have been obvious to a person of ordinary skill in the art at the

time of the invention. All the claimed elements have been disclosed by the prior art for use in the same manner as claimed. Thus it would have been obvious to one of ordinary skill in the art to have prepared solutions as supposed to suspensions of corticosteroids and to have employing other active agents in the said formulations and device for opening the line of such therapy to more patients.

Applicant also argues that "While Blondino et al discloses a solution formulation of budesonide (a C-21 OH steroid) in HFA propellant, there is no recognition whatsoever of a chemical stability problem or how to solve it". This is not persuasive. Blondino meets the formulation of the instant claims. It does not need to recognize the problem that inventors of the instant claims were concerned with to meet obviousness. To meet obviousness, prior art does not need to recognize or resolve the same problem as claimed. In *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007), Court ruled that, obviousness can come from the references or from the knowledge of a person having ordinary skill in the art. In fact, the Supreme Court stated that the Federal Circuit had erred in four ways, one of which is "by holding that courts and patent examiners should look only to the problem the patentee was trying to solve" and second is "by assuming that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem". See KSR, 82 USPQ2d at 1397.

With regard to the Double Patenting rejection of claims over co-pending Application No. 11/061,529, Applicant stated that "Applicants enclose a terminal

disclaimer that disclaims the terminal part …..". However, there is **no** terminal disclaimer filed, therefore the rejection remains pending.

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616